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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,980	09/30/2003	Yaron Iian	Enz-64 (CIP)	9089

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,980	IIAN ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/26/2005.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-115 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) 13-21,28-42,67-74,77-80 and 111-115 is/are objected to.

8)☒ Claim(s) 1-12, 22-27, 43-66, 75-76 and 81-110 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 13-21, 28-42, 68-74, 77-80 and 111-115 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Of note, claim 67 is a dependent claim that does not disclose a claim on which it depends. Therefore, there is no possible group to which this claim belongs.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-6, 11, 43-54, 59-60, 75-76, 97, 109 and 110, drawn to a method of treatment in a mammalian subject comprising administering an intermediary metabolite, are classified in class 424, subclass 1.11.

II. Claims 2-6 and 26, drawn to a method of treatment in a mammalian subject comprising administering a T cell ligand, are classified in class 424, subclass 154.1.

III. Claims 7, 55, 76, 93 and 110, drawn to a screening assay for an analogue or derivative of an intermediary metabolite and treatment using NKT cells,

antigen presenting cells and an analogue or derivative of said intermediary metabolite, are classified in class 435, subclass 5.

IV. Claims 8, 56, 76, 94 and 110, drawn to an screening assay for an analogue or derivative of an intermediary metabolite and treatment using various combinations of NKT cell, BSA, an analogue or derivative of said intermediary metabolite and antigen presenting cells, are classified in class 435, subclass 5.

V. Claims 9, 10, 57-58, 75-76, 81-92, 95-96 and 109-110, drawn to an method of treatment using cells *ex vivo* in the presence of an intermediary metabolite, are classified in class 424, subclass 93.21.

VI. Claims 12, 61-63 and 99, drawn to a therapeutic composition comprising an intermediary metabolite, are classified in class 514, subclass 12.

VII. Claim 22, drawn to an *in vitro* screening assay for an analogue or derivative of a T cell receptor ligand and using a combination of antigen presenting cells, NKT cells and derivative of said T cell receptor ligand, is classified in class 435, subclass 5.

VIII. Claim 23, drawn to an *in vitro* screening assay for an analogue or derivative of a T cell receptor ligand and treatment using BSA, NKT cells, and said analogue of a T cell receptor ligand, is classified in class 435, subclass 5.

IX. Claims 24-25, drawn to a method of treatment using cells *ex vivo* in the presence of T cell receptor ligand, are classified in class 424, subclass 154.1.

X. Claim 27, drawn to therapeutic composition comprising T cell receptor ligands, is classified in class 514, subclass 12.

XI. Claims 64-66 and 100-108, drawn to a use of an intermediary metabolite in the manufacture of a composition, are classified in class 514, subclass 12.

Groups I, II, III, IV, V, VII, VIII, IX and XI are all unrelated to each other. Briefly, Groups I and II are drawn to a method of treatment; these groups, however, are drawn to some intermediary metabolite and some T cell receptor ligand, respectively. Groups III and IV, drawn to a screening assay, use different starting materials in each method. Groups V and IX are drawn to a method of treatment using cells *ex vivo*, although Group V uses an intermediary metabolite while Group IX uses a T cell receptor ligand. Groups VII and VIII are drawn to a screening assay; each assay, however, requires different starting materials. Lastly, Group XI is drawn to a method of making an intermediary metabolite. Because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products, each method is patentably distinct.

Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the specification does not disclose a combined use for the different compositions in Group VI and X. Group VI is drawn to a composition comprising an intermediary metabolite. In contrast, Group X is drawn to a composition comprising a T cell ligand. In addition, the different compositions have a materially different design or structure. Thus, Groups VI and X are patentably distinct.

Group VI is related to Groups I, III, IV and V as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). Group VI is drawn to a therapeutic composition comprising an intermediary metabolite while groups I, III, IV and V are drawn to methods of treatment comprising an intermediary metabolite. The intermediary metabolite ceramide, for example, may be used to induce apoptosis *in vitro* to study cell programmed death. Because Group VI is a composition that can be used in a materially different process than those claimed in Groups I, III, IV and V, the inventions are patentably distinct.

Inventions VI and II, VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the specification does not disclose a use for a therapeutic composition

comprising an intermediary metabolite in the methods described in Groups II, VII, VIII and IX. Thus, the inventions are patentably distinct.

Inventions X and I, II, III, IV, V, VI, VII, VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group X is drawn to a method of treatment comprising administering a T cell receptor ligand. In contrast, Groups I, III, IV, V, VI, VII, VIII and XI are drawn to both product and method claims comprising an intermediary metabolite, a T cell ligand, a derivative or analogue of an intermediary metabolite and a derivative or analogue of a T cell receptor ligand. The specification does not disclose a combined use for a method of treatment comprising administering a T cell ligand with Groups I, III, IV, V, VI, VII, VIII and XI. Thus, these inventions are patentably distinct.

Inventions X and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product, a composition comprising T cell receptor ligands, may be used in to isolate and purify bacterial superantigens. Because the claimed product can be used in a materially different process than the method of treating cell *ex vivo* claimed in Group IX, the inventions are patentably distinct.

Election of Species

A. *A further election of species is required following election of one group from I-XI.*

This application contains claims directed to the following patentably distinct species:

A. a specific intermediary metabolite, and

B. a specific T cell ligand.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are structurally different. Additionally, the different structures have different functional effects. Thus, these species are distinct. *Applicant is required to elect a single intermediary metabolite or T cell ligand, or an analogue or derivative thereof.*

B. *A further election of species is required following election of one group from I-XI.*

The specification of this application is directed to the following patentably distinct species of disease to be treated:

i. Gaucher's Disease,

ii. Hepatitis Virus C,

iii. Type II Diabetes,

iv. Colitis,

v. Melanoma,

vi. tumor, and

vii. lung metastasis.

The different species of disease states are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of treating each disease produces physiologically different effects. Additionally, the specification does not disclose the combined treatment of the different disease states. Thus, these species are distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic because no claim is limited to a specific disease or product for treatment.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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